# Perspectives on Local Manufacture of Contraceptives in Developing Countries

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**August 1997**

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USAID Contract No. DPE-3056-C-00-1040-00

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This report is part of a series of PROFIT studies, which address various topics related to private sector family planning. The studies grow out of PROFIT subprojects within the following three strategic areas: innovative investments, private health care providers, and employer-provided services.

PROFIT is supported by the Office of Population in the Center for Population, Health and Nutrition (G/PHN/POP) of the U.S. Agency for International Development (USAID), cooperative agreement number DPE-3056-C-00-1040-00.

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## *ABSTRACT*

This report from the Promoting Financial Investments and Transfers (PROFIT ) Project examines the issue of donors' support for the local manufacture of contraceptives in developing countries. Decisions about the feasibility and advisability of local manufacturing must be made on the basis of the factors specific to the particular project and location. Donors and manufacturers should assess not only the economic and technical feasibility of potential projects but also the social and political factors that may affect the success of the venture. These include the interests, motivations, actions, and interactions of the parties involved, which may include multinational and local pharmaceutical firms, donors, government officials, and consumers.

The report draws on the large body of existing technical and economic information related to this question but is based primarily on dozens of interviews conducted by the author with people involved in and knowledgeable about local manufacturing of contraceptives. The perspectives and opinions expressed are those of the interviewees.

## *ACKNOWLEDGMENTS*

The author would like to thank Ann Sherpick of PROFIT for her help and advice during the research and writing of this paper. The author also would like to acknowledge Barbara Janowitz of Family Health International and Susan Mitchell of PROFIT for their careful reading of the manuscript. Finally, the author expresses his sincere appreciation to the many individuals who gave their time to be interviewed; without their participation, this paper could not have been written. Linda Griffin Kean, Consultant to PROFIT, edited and revised the final draft.

## *CONTENTS*

## *TABLES AND FIGURES*

## *ACRONYMS*

| | |
|---|---|
| FPLM | Family Planning Logistics and Management |
| GMP | Good Manufacturing Practices |
| IPPF | International Planned Parenthood Federation |
| IUD | intrauterine device |
| NAFTA | North American Free Trade Agreement |
| PATH | Program for Appropriate Technology in Health |
| PIACT | Program for the Introduction and Adaptation of Contra-ceptive Technology |
| PROFIT | Promoting Financial Investments and Transfers Project |
| UNFPA | United Nations Population Fund |
| USAID | U.S. Agency for International Development |
| WHO | World Health Organization |

# *EXECUTIVE SUMMARY*

This report of the Promoting Financial Investments and Transfers (PROFIT) Project examines the factors that determine donors' involvement in and financial support for local manufacture of contraceptives in developing countries. The author outlines a variety of perspectives on this topic, using the results of a literature survey and a series of interviews among people involved in local manufacturing ventures.

Typically, donors assess the potential of a local manufacturing project by conducting a series of feasibility studies. They examine the potential demand for the product(s) to be manufactured, the capabilities and capacities of the local partner(s), and financial projections about startup costs, operating costs, and sales revenue. However, in addition to these market-based considerations, the eventual success of the enterprise will also depend on social and political factors—specifically, the interests, motivations, actions, and interactions of the people and organizations that influence and are affected by its operations. Decision makers should seek a more complete understanding of these social and political factors when assessing the feasibility and advisability of any potential local manufacturing project.

This report draws on a literature review of technical and economic information produced by the Program for Appropriate Technology in Health (PATH), the United Nations Population Fund (UNFPA), and PROFIT. In addition, the author interviewed dozens of people knowledgeable about and involved in local manufacturing operations, using a similar set of questions with those on all sides of the various issues involved. The interviewees included family planning experts and representatives of contraceptive manufacturers in several countries, donors agencies and partners, and a private U.S. foundation. The perspectives and opinions offered in this paper are those of the interviewees.

These interviews revealed that, as may be expected, those people who are affected by decisions about local production of contraceptives work to serve their own interests. When the interests of these people or groups coincide, they form coalitions. When their interests conflict, they struggle for influence. The result is that decisions about local manufacturing may reflect not only the economic or technical feasibility of the project but also the influence of people or groups that can wield money and power.

## Factors that Affect Local Manufacturing

Donors assessing potential local manufacturing operations should consider the full range of economic and technical *and* political and social factors that will affect the success of the enterprise:

- Demand for contraception: The method mix varies by region and country, as well as by age, marital status, reproductive intentions, and other social and demographic factors. Demand for the product(s) will be affected by these and other demographic, cultural, and behavioral factors.

- Profitability: The production of contraceptives is capital-intensive and enjoys significant and increasing returns to scale—that is, unit production costs decrease as the volume of production increases. Production volume must be sufficient to keep the costs, and thereby the price to consumers, low enough to be competitive in the market. The ability of the new facility to sustain a profitable production volume will be affected by the current and future availability of relevant products from imports, local production, and/or government and donor distribution.

- Trade restrictions: The import of contraceptive products and/or the export of locally manufactured contraceptives may be restricted or regulated by the government. For example, imports may be limited by type, volume, or time period. The ability of companies to repatriate their profits may be circumscribed. Or imports and exports may be subject to tariffs, inspections, or local-content restrictions. The ability of the local manufacturing operation to import, license, or export contraceptive products may be limited by such laws and regulations.

- Potential public-private partnerships: There may be an opportunity to establish or promote a partnership among donors, government agencies, multinational or local companies, and/or local investors. Partnerships can improve the viability of the local manufacturing operation by tapping and leveraging the partners' resources and capacities, including financial and human resources, market research and intelligence, sales and distribution networks, and publicity and public information capabilities.

- Intellectual property protection: Local laws concerning the protection of patents, trademarks, and other intellectual property may affect the willingness of major multinational companies to establish local manufacturing facilities or to license their brands for local production.

- Donated commodities: Public sector programs that provide free or low-cost contraceptive products to low-income consumers will affect overall demand for privately marketed contraceptives. Despite efforts to make donated commodities less appealing to consumers

who are willing to pay for contraceptives, there is usually some "leakage" of donated contraceptive supplies into the marketplace.

- Corruption: Corruption among businesspeople or government officials can be a severe market distortion. Many multinational companies are unwilling to enter markets where corruption and bribery may be endemic.

- Government and donor policies to promote local production: Some governments—and the donors that work with them—implement explicit policies to promote local production of contraceptives even when the venture does not meet strict profitability criteria. These policies may reflect a desire to utilize available local inputs or production capacity; to develop local infrastructure, skills, or employment opportunities; to make contraceptive products more culturally acceptable; or to boost national pride.

- Quality assurance: The ability of some local manufacturers to produce high-quality products may be compromised by insufficient capital, a desire to lower production costs (e.g., to compete with donated supplies), outmoded production facilities, lax regulatory and inspection systems, poor management, and a lack of skills. Poor quality assurance can make multinational firms unwilling to license their product(s) or to participate in partnership arrangements. Poor quality also limits demand for the product(s) and thereby compromises the long-term viability of the manufacturing operation.

## The Role of Donors

Donors influence the local manufacture of contraceptives in several ways. The most important may be to limit the ability of local firms to profitably produce contraceptive products: unless they produce for donors, these firms are forced to compete with donated commodities that are available in the public sector for free or at subsidized prices (which may be below cost).

Even when local firms seek to produce for donors, their ability to compete may be limited by the effect of donor procurement on prevailing prices for contraceptives. For example, by being able to purchase huge quantities of commodities, donors may be to negotiate prices that are too low to be profitable for local producers. In addition, the procurement practices of some donors are restricted by law. For example, USAID must procure from U.S. producers and has only limited ability to buy local products.

The quality of contraceptive products can be directly and indirectly affected by donor programs to support local manufacture. Donors naturally insist on adherence to Good Manufacturing Practices (GMP) and have helped to develop quality standards for certain products. Nonetheless, limited

technical expertise or inadequate regulatory and inspection mechanisms in some countries may mean that donors are unwitting accomplices in the manufacture of poorer-quality products.

Finally, the policies and programs of donors may reflect other motivations that distort the market for local products. For example, in addition to their relief and development mandates, national aid agencies may be required to further national security interests, accommodate domestic or international political realities, or conform to certain ideological objectives. The programs and priorities of multinational donor agencies often reflect their broad missions and their funding sources. For example, the World Bank has traditionally assessed potential loans for local contraceptive manufacture on strict profitability criteria, whereas the United Nations Population Fund (UNFPA) has traditionally used a number of non-economic criteria.

## The Future of Local Manufacturing

Donors will no doubt continue to be involved in the local manufacture of contraceptive products in developing countries. However, the most successful ventures are likely to be those initiated in collaboration and partnership with the private sector. Global trends toward economic liberalization will continue to limit the role of government-owned production facilities and will increase competition among private firms.

The local manufacturing projects funded by donors in the future should therefore adhere to stricter economic criteria. The producers should be subject to market incentives that reward high-quality, efficient production. Given the general decrease in commodity donations, the role of donors in the future may revolve around helping developing country governments to:

- more accurately assess the feasibility of local production operations
- support economically viable local manufacturing facilities
- efficiently procure commodities on the international market when local production proves impractical.

# 1. INTRODUCTION

This report examines the factors that affect donor involvement in and funding of the local manufacture of contraceptives in developing countries. The author outlines a variety of perspectives on this topic, using the results of a literature survey and a series of interviews among people involved in local manufacturing ventures.

Typically, donors assessing a potential local manufacturing project undertake a series of feasibility studies to assess its economic and technical merits, including demand for the product(s), the technical capabilities of the partner(s), and the financial feasibility of the operation (Free et al., 1984; PATH, 1990). These economic and technical assessments are essential, but social and political factors can also affect the ultimate success of the venture and should therefore also be considered by donors. The key to understanding the relevance of these social and political factors is to learn who is involved in the process and to seek to understand their motivations. This report offers insight into the interests, motivations, actions, and interactions of the people and organizations that influence and are affected by decisions about local contraceptive production.

The report draws on a literature review of the large body of technical and economic information produced by the Program for Appropriate Technology in Health (PATH), the United Nations Population Fund (UNFPA), and PROFIT, among others. The report also draws upon interviews conducted by the author with dozens of people knowledgeable about and involved in local manufacturing operations, including family planning experts and representatives of contraceptive manufacturers in several countries, donor agencies and partners, and a private U.S. foundation (see Appendix 1). The author asked a similar set of questions of each person to help uncover their common and conflicting perspectives. The opinions and perspectives included in this paper come from these interviews, particularly those presented in boxes titled "Perspective."

The interviews revealed that, as may be expected, those involved in making decisions about local production of contraceptives work to serve the interests of their organizations. When their interests coincide, they often form coalitions. When their interests conflict, they struggle for influence. The outcome may reflect the influence of money and power as well as—or instead of—the results of a rational decision-making process about the economic and technical merits of the project and the best interests of the country.

The remainder of this report examines the factors that donors should consider when making decisions about whether, where, and how to establish local contraceptive manufacturing facilities. Section 2 reviews the global demand and supply for contraceptives, including current types of manufacturing arrangements. This review can help donors identify the types of people and organizations that might be affected by and, in turn, might affect a local manufacturing venture. Section 3 outlines some

of the factors involved in decisions about local manufacturing, including profitability, general market factors, and market distortions such as trade policies, the presence in the market of donated commodities, and corruption. Section 4 outlines how donors influence the market for locally manufactured products through procurement of contraceptive commodities, funding of local production facilities, and other programs and policies. Section 5 identifies some trends for the future of local manufacturing and their implications for donor involvement. Appendix 2 comprises a list of questions that donors should consider when making decisions about local manufacturing.

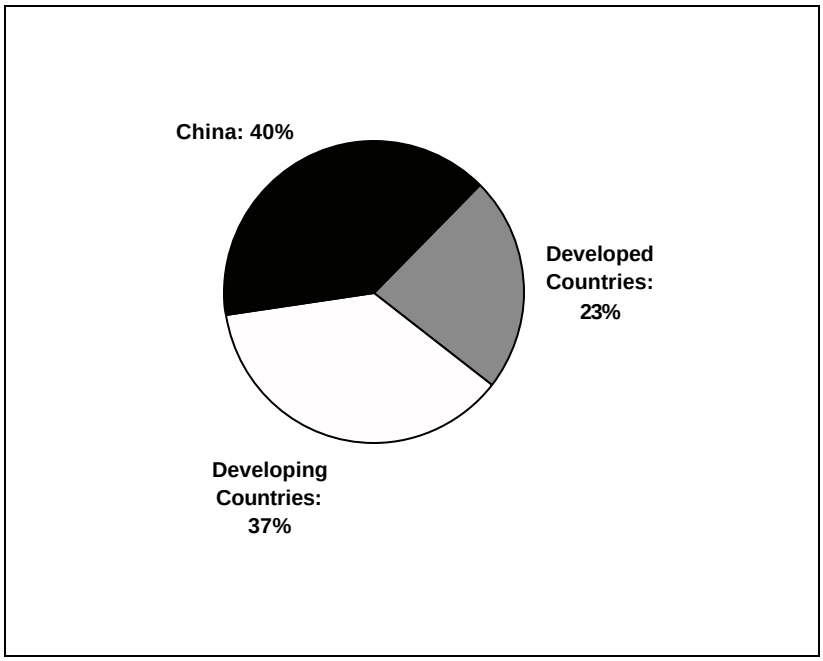
# 2. GLOBAL CONTRACEPTIVE DEMAND AND SUPPLY

## 2.1 Demand

Worldwide demand for contraception is large and growing. More than 50 percent of the world's couples of reproductive age (15–49 years) currently use a modern method of contraception to prevent pregnancy (U.N., 1994). Figure 1 shows the disproportionately large demand for contraception in developing countries, especially China. In developing countries, the contraceptive prevalence rate—the percent of married women of reproductive age using modern contraceptive methods—is up from an estimated 14 percent in 1960–1965 to more than 50 percent today (see Figure 2). The increase in demand is due to a variety of factors including economic growth, increasing secularization, the improved status and education of women, and increased availability of contraceptives. Contraceptive use has also grown in absolute terms due to the growth of the world's population from 4 billion in 1975 to 5.8 billion in 1996.

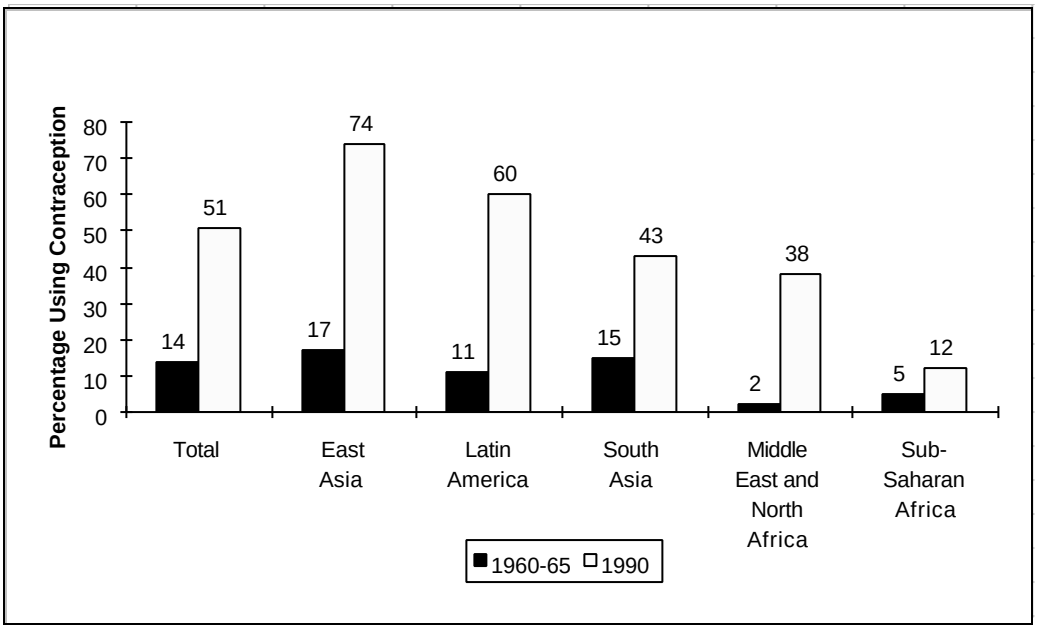
## Figure 1. Global Demand for Contraception

**(percent of total users)**




Source: U.N., 1994

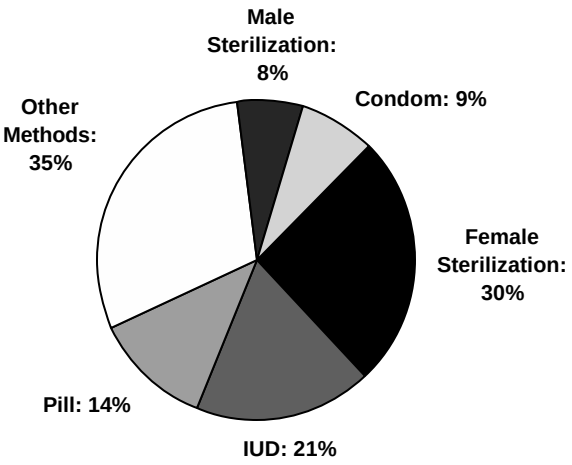
**Figure 2. Contraceptive Prevalence in Developing Countries, 1960–1965 and 1990**




Source: Ross and Frankenberg, 1993.

The most popular contraceptive method in the world is female sterilization, used by nearly 30 percent of contraceptive users, followed by the IUD (21 percent) and the pill (14 percent) (see Figure 3). Method mix varies by region and country and, at the individual level, by age, marital status, reproductive intentions, and other social and demographic factors. Most consumers do not have access to the full range of contraceptive methods. This helps to explain why certain countries, programs, and even clinics overwhelmingly favor particular methods—a phenomenon that has concerned researchers, program developers, and women's groups for years. In part, this tendency reflects the differing preferences of contraceptive acceptors in these countries, but it also reflects provider biases and implicit and explicit procurement decisions taken by national family planning programs.

**Figure 3. Global Contraceptive Method Mix among Contraceptive Users**




"Other Methods" includes injectables, withdrawal, and vaginal methods

Source: U.N., 1994.

## 2.2 Supply

The production of contraceptive pharmaceutical products and devices is a multibillion-dollar global industry. More than 500 million couples use modern methods of contraception to avert pregnancy, and slightly more than a third of that number are sterilized. The rest—about 360 million couples—depend on such products as IUDs, oral contraceptives, and injectables.

Global contraceptive production is dominated by a few large multinational pharmaceutical firms, although smaller firms have found market niches in some developing countries. Excluding output from China and India, only a small proportion of world production takes place in developing countries. The principal reason is that pharmaceutical production in general, and contraceptive production in particular, is capital-intensive. In addition, there are increasing returns to scale—that is, unit production costs decrease as the volume of production increases. Production decisions that are based purely on economic considerations are driven by these two factors.

A small group of multinational pharmaceutical corporations dominates worldwide production of hormonal contraceptives, including Schering AG, Ortho, Wyeth-Ayerst, Organon, and Pharmacia & Upjohn. Similarly, global manufacture of condoms is dominated by such companies as London International, Sagami, and Okomota. Global IUD production (excluding that occurring in China) is divided among a small number of multinationals and smaller private companies in both developed and developing countries. The biggest producers are Finishing Enterprises, Inc. (USA), Leiras (Finland), Organon (Netherlands), and Famy Care, Ltd. (India).

The fact that production of contraceptives is concentrated with a handful of multinational firms implies that the industry may be an oligopoly. Oligopolistic manufacturers have a vested interest in keeping new producers out of the market because their profits depend on their ability to maintain market share and to segment their customers. One study of the U.S. condom industry concluded that the industry is naturally oligopolistic, mainly due to such barriers to entry by new firms as price inelasticity and a limited market (Murphy, 1980).

Although contraceptive producers enjoy high profits—one characteristic of oligopoly—this does not necessarily imply that there is collusion or cartels in this industry. Fortunately for consumers, the pharmaceutical industry faces a fairly competitive market for contraceptives. There *are* competing products on the market, and decisions about their sale and distribution are not always made by producers. However, neither are such decisions made directly by con-sumers—in most cases, large purchasers exert a great deal of control over sales and distribution. For example, the United Nations Population Fund (UNFPA) and the U.S. Agency for International Development (USAID) purchase large quantities of commodities and can negotiate low prices, which they can pass along to consumers. To the extent that a handful of donors and distributors control the market, the situation might be described as oligopsony—that is, there are few buyers to counter the market power and high profits of oligopolistic producers (Galbraith, 1952). These few large purchasers make decisions that affect the choice and availability of contraceptives for large population groups. Furthermore, individual consumers' choices about product brands are usually made by their public or private sector health care providers.

The large, multinational pharmaceutical manufacturers realize that the majority of the world's population—their potential customers—lives in developing countries. They employ a variety of mechanisms to supply this burgeoning market.

### 2.2.1 Export to Developing Countries

Labor-intensive industries such as clothing and textiles commonly locate manufacturing facilities in developing countries to take advantage of lower labor costs. In contrast, as noted, the pharmaceutical industry is capital-intensive and enjoys increasing returns to scale. These characteristics lead most multinational pharmaceutical firms to locate production facilities at home and to export products to their developing country markets. Theoretically, these characteristics also mean that large-scale home-

country production for export is most beneficial to buyers—governments, donors, and individual consumers.

### 2.2.2 Local Subsidiaries

Many governments make it difficult for pharmaceutical companies and others to import contraceptives (discussed in more detail in Section 3). Therefore, larger pharmaceutical firms often establish wholly owned subsidiaries in such countries to manufacture their products locally. For example, of the 208 multinational pharmaceutical companies that operated in Mexico in 1977, more than half were 100 percent owned by a foreign parent corporation (United Nations Centre on Transnational Corporations, 1984, 50–52). The potential profitability of a local subsidiary may be higher than for other ownership arrangements, but the risks are also higher—the parent company can lose its entire investment, for example, through nationalization.

### 2.2.3 Licensing Agreements

In many cases, the multinational firms manage their risk by selling site licenses to local pharmaceutical firms, under which the local company pays the multinational firm for the privilege of producing its pharmaceutical brand(s). Typically, the local manufacturer pays an up-front fee and a percentage of gross revenues.

Site license contracts usually stipulate that the parent company can make regular inspections of the overseas facilities. To maintain a strong reputation in an industry as competitive and complex as pharmaceuticals, the parent company must retain the right to stop production in factories unable or unwilling to maintain Good Manufacturing Practices (GMP).

**Perspective**

**A Multinational Site License in Algeria**

Site licensing arrangements can involve a bewildering variety of stakeholders. A representative of a German pharmaceutical company interviewed for this report described his company's plans to build an oral contraceptive factory in partnership with the Algerian government. The financing for this German-Algerian project was to come from the French government, and the principal buyer was a multilateral donor, UNFPA.

### 2.2.4 Public-Private Partnerships

A hybrid mechanism for multinational firms to produce contraceptives in developing countries is through public-private partnerships. Such partnerships are relatively uncommon and generally occur in developing countries that have low technical capacities and strong centralized governments. The partnerships may involve a multinational pharmaceutical company, the state, and perhaps local investors or manufacturers. One example, is the partnership among Wyeth, the government of India, and local investors to produce oral contraceptives. Another is Schering's local manufacturing facility in Pakistan, which is 51 percent owned by the Pakistani government.

**Perspective**

**Technology Transfers**

Some companies are able to profit from selling the technology or the "know-how" for production of contraceptives. In the case of Copper T IUDs, both U.S. and Indian manufacturers have provided technical assistance to governments and firms interested in initiating local production. Such technology transfers are also common in the condom industry, where formulations and even complete production lines are sold.

### 2.2.5 Production by Local Entities

Not all local manufacture of contraceptives is by multinational firms. In fact, government production of various methods in China and India necessarily accounts for a large proportion of the total global supply because of the size of the markets in these countries. Who are the local producers, and what are the advantages and disadvantages of local production without the involvement of multinational corporations?

Some local companies have the capacity to produce nearly every type of contraceptive, including oral contraceptives, IUDs, condoms, and even diaphragms. This production takes place under a variety of institutional arrangements.

Some small, entrepreneurial, independent pharmaceutical companies manufacture products to fill a local market niche. These local producers may find it difficult to counteract the appeal of imported goods, but their inexpensive local product and familiar packaging in the local language can attract ready buyers. Their market niche can grow larger if the government levies high import duties or otherwise limits imports of competing brands.

Another form of local production involves site licenses negotiated with large, international pharmaceutical firms, as noted above. Under such arrangements, a local pharmaceutical company must demonstrate to the licenser that an adequate market exists for the product and that local production will meet the quality standards of the parent corporation.

**Perspective**

### Indian Contraceptive Manufacturers Follow Different Marketing Strategies

J.K. Chemicals, a condom manufacturer, and Famy Care, an IUD manufacturer, are both private, Indian-owned companies, but they have found success by serving very different markets. The success of J.K. Chemicals is based on its domestic sales. Although the company exports its Kama Sutra condoms to South Africa, the Middle East, and Eastern Europe, most of annual production of 250 million units is bought by the Indian government for public sector distribution. In contrast, Famy Care's production is led by exports. The firm is licensed by the Population Council to produce the Copper T 380A IUD, which it exports to 70 countries, primarily through UNFPA.

A final category of local manufacture occurs in government-owned facilities and accounts for most cases of donor involvement in local manufacture. For example, UNFPA has supported technical upgrades or "turn-key" projects in India, Vietnam, and a dozen cities in China. Similarly, as mentioned, the government of France plans to finance a public-private partnership to produce oral contraceptives in Algeria.

## PERSPECTIVE

### Problems at a Condom Manufacturing Plant in Vietnam

Vietnam, which has a large public sector market for condoms and produces high-quality latex, seems a natural site for condom production. Yet one condom manufacturing facility, MERUFA, funded by UNFPA, was beset with problems from its inception. Below is UNFPA's own description of the MERUFA factory, which outlines how the location of the factory reflected political rather than practical considerations:

> The location and layout of the facility do not facilitate maintenance of a controlled manufacturing environment. The site is too small and does not readily accommodate the production line and allow for expansion. Product flows are convoluted, requiring unnecessary handling that adversely affects productivity and product quality. The lack of an adequate supply of electricity has continued to hamper operations. Power blackouts and voltage surges play havoc with motors and controllers. Substandard wiring within the facility also creates safety and maintenance hazards (UNFPA, 1995).

No economic or engineering study could explain, in retrospect, why a condom factory was sited in such a facility. In fact, political processes led the Vietnamese government to insist upon this particular location and led UNFPA to acquiesce in that decision.

# 3. FACTORS AFFECTING LOCAL MANUFACTURING

## 3.1 Profitability

Prospective contraceptive manufacturing projects in developing countries must meet a variety of criteria before local or multinational firms will invest. First and foremost, such projects must make economic sense. Private companies will not invest if there is no promise of a competitive return on their investment. In fact, for multinational companies, the anticipated return must generally be greater than the potential return on other possible investments. Why? Multinationals would generally prefer to produce at home and export their product, and because overseas manufacturing and, in particular, manufacturing in developing countries is more complex, higher profits are needed to compensate for the added costs and risks.

Profitability depends on several factors. The first is the market share the product can command. This depends not only upon the size of the population and the demand for contraceptives, but also upon local competition, competitors' prices, and the population's ability to pay for the goods in question. When it is not feasible to export to other countries, the potential market in the country of manufacture must be sufficient to ensure profitability. Table 1 outlines one organization's analysis of the minimum production levels for profitable manufacturing.

Finally, profitability may also depend upon economies of scale. As noted, contraceptive manufacture is a capital-intensive process with increasing returns to scale. Production of the IUD is an extreme case: at efficient levels of production, a single factory can produce the entire demand for a small country in a month or two. Unless substantial opportunities exist for export, production of the IUD would be unprofitable in smaller developing countries. Experts interviewed for this report noted that in-country health professionals and family planning experts often overestimate the size of local markets and underestimate the difficulty of exporting.

**Table 1. Sample Analysis of Minimum Production Levels for Profitable Contraceptive Manufacturing**

| Method | Minimum Production for Profitability |
|---|---|
| Oral Contraceptives (cycles) | 15 million |
| Condoms (units) | 70 million |
| IUDs (devices) | 1 million |
| Injectables (doses) | 5-10 million |

Source: PATH, 1991.

**Perspective**

### When Demand Is Not Enough

Even if a country has a large population that has a strong desire for contraception, local private sector production of contraceptives may not be feasible. Bangladesh is an example. With a population of 120 million and modern contraceptive prevalence of 36 percent, the potential market for contraception is tremendous. Nonetheless, the country's extreme poverty has prevented local production by private firms, because few Bangladeshis can afford to pay the full price of contraceptives in the private market.

Donors also hesitate to subsidize the manufacture of contraceptives in Bangladesh. Even if the local infrastructure could accommodate modern production facilities, high costs and production difficulties mean that local manufacture is not a cost-effective alternative to buying high-quality, low-cost contraceptive commodities on the international market. In the view of one international expert, "The money spent on buying condom machines for a country like Bangladesh would be better spent on buying sewing machines for local women."

## 3.2 Market Distortions

Profitability is not the only criterion manufacturers consider when making decisions about contraceptive production in developing countries. Producers must also consider the risk involved. Multinational firms generally consider overseas investments to be high-risk because it is more difficult to

control internal manufacturing processes and because they exert little if any control over the local political and economic environment. Because of the threat of war, strikes, inflation, expropriation, and natural disasters, firms usually seek a higher return on their investments in developing countries. Other firms avoid such investments unless they are necessary to overcome market distortions that affect the ability of companies to manufacture, distribute, and sell their products. Such distortions may stem from trade policies, the presence of donated contraceptive commodities, corruption, and other government and donor policies that encourage or require local production.

### 3.2.1 Trade Policies

The most obvious market distortions stem from trade policies that affect the economic incentives in the marketplace. Such policies may be designed to promote local production, reduce unemployment, save scarce foreign currency, or earn foreign exchange.

Among the most common of the market-distorting trade policies are tariffs that force companies to pay large duties for importing their products instead of producing locally. Such tariffs—often part of an "import substitution" or "infant industry protection" policy—are designed to make local products more competitive (i.e., by raising the price of competing products). These measures stem from an assumption that temporary protection from lower-cost foreign competition will allow a country's manufacturing sector to more quickly move along a "learning curve" and eventually to become competitive on the world market. International firms in countries with high import tariffs often are forced to manufacture their products locally if they want to compete in the local market. Infant industry protection was popular in Latin America, but such tariffs are now being lowered or abolished under recent trade agreements and as a result of structural adjustment and other economic liberalization measures.

Other, nontariff import restrictions also affect decisions about local manufacture. For example, pharmaceutical manufacturers report being able to import a product only for a limited time into certain countries, particularly in Latin America. After that period, the companies face restrictions that force them to withdraw the product from the market or manufacture it locally.

Laws concerning patent and/or formula protection also may act as a market distortion. Some countries have actively used patent and trademark laws to encourage local production. For example, Brazil abolished patents for pharmaceuticals in 1969 to strengthen the position of domestic manufacturers (United Nations Centre on Transnational Corporations, 1984). More recently, however, many developing countries simply have not had the resources to enforce existing national and international trademark and patent laws. Pharmaceutical companies that have significant resources invested in their formulations, whether for contraceptives or other products, naturally hesitate before setting up manufacturing operations in countries with weak patent protection, or where manufacturing processes, but not products, can be patented.

Some countries require full or partial local ownership (or management) of manufacturing facilities. Where such laws are in place, foreign companies wishing to manufacture locally face the added difficulty of finding qualified partners. Similar requirements—which are not usually relevant to contraceptive manufacture—govern the amount of "local content" that must be included in manufactured goods. Such requirements do not exist for hormonal contraceptive manufacture because even large multinational firms often import the steroids they use as raw material. However, a country assessment of the potential for innovative investments in Brazil noted that condom manufacturers there face local sourcing requirements that require them to purchase half of their latex domestically (PROFIT, 1992). Another source notes that "in the past, shortages of high quality Brazilian latex rubber and strict import quotas on imported rubber have left manufacturers without adequate raw materials for production" (PATH, 1991).

Policies that forbid or limit the repatriation of profits also distort the market. Many pharmaceutical company representatives interviewed for this report noted that profit repatriation restrictions presented a difficult problem. Another, related type of restriction governs currency conversion—the ability to convert profits to a hard currency at favorable exchange rates. This type of restriction may be particularly onerous in countries with artificially inflated exchange rates.

**Perspective**

**Currency Conversion in Indonesia**

One representative of a cooperating agency of USAID characterized currency conversion restrictions as the "final nail in the coffin," responsible for precluding local manufacture in many countries that are short of hard currency. He speculated that a steady supply of hard currency can facilitate local manufacture by increasing the willingness of governments to buy local currency at reasonable exchange rates.

For example, multinational pharmaceutical companies have invested in the local manufacture of contraceptives in Indonesia, with much success. The fact that Indonesia enjoys a steady flow of petrodollars to the national treasury may make the Indonesian government more willing to offer foreign firms more reasonable exchange rates on the local currency than those governments that face chronic shortages of hard currency.

### 3.2.2 Donated Commodities

Another market distortion that impinges on local production of contraceptives is the presence of donated commodities in public sector or commercial outlets. In most developing countries, such

donated products are available free of charge or well below market price for lower-income consumers. Local producers justifiably worry about "leakage" of donated supplies into the market to meet the demand of customers who could afford to buy contraceptives on the private market.

To protect the viability of the local private sector, donors often try to "segment" the market by making their products less attractive to wealthier consumers. For example, USAID avoids such "high end" products as tri-phaisic pills. Similarly, donated contraceptives are usually distributed in plain, relatively unattractive packaging. Nonetheless, products meant for the public sector still find their way into private markets at lower-than-market prices. For example, the fact that the condom market in Zimbabwe was "flooded" with free products from international donors was one reason (among others) cited by several foreign investors who declined to fund a local condom manufacturing facility there.

### 3.2.3 Corruption

Corruption represents a severe market distortion in many countries. Multinationals may find their access to government ministries and other key government offices blocked if they refuse to offer bribes or kickbacks. Similarly, officials may force international manufacturers to work with certain local companies or individuals. A representative of one large pharmaceutical firm described corruption as a "big problem" and noted that his company had pulled out of at least one country for this reason. He added that U.S. companies sometimes find themselves at a disadvantage because they are unable to work with local firms that will not adhere to strict U.S. codes of ethical business conduct, although he felt that U.S. firms were better off in the long run by not participating in such systemic corruption.

### 3.2.4 Other Government and Donor Policies

Another factor that can distort local markets are explicit policies by governments—and the donors that support them—to promote local production of contraceptives. The rationales for such efforts include:

- availability of local inputs
- existence of excess pharmaceutical production capacity
- development of local infrastructure, skills, and employment opportunities
- opportunities to produce culturally appropriate packaging
- boosting national pride through import substitution (Free et al., 1984).

One example of the potential influence of such criteria comes from Egypt. A series of feasibility assessments was conducted by the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) in 1987 and 1988 and by PROFIT in 1995 to examine the possibility of producing Copper T IUDs in Egypt. The impetus for each of these reports was the Egyptian government's strong desire to produce contraceptives locally. The PROFIT researcher noted that the Egyptians argued for local production of IUDs even though estimates put their cost at twice that of competing imports. Among the arguments were national pride, import substitution, and the appropriate use of Egypt's existing medical plastics technology.

Similarly, a UNFPA assessment of condom production in Vietnam cited a local supply of high-grade latex, high demand, and low supply as rationales for local production (UNFPA, 1995). A previous PATH report to UNFPA had specified that a major cause of the low supply was the chronic shortage of foreign exchange (PATH, 1991)—a condition that would also make local production less attractive to international manufacturers, as noted above.

**Perspective**

### Ideological Arguments for Local Production

A donor representative noted that many developing countries justify local production of contraceptives on ideological grounds. As he put it, developing countries do not want to appear dependent on donor countries, and local manufacture helps political leaders argue to their constituents that their countries are not dumping grounds for Western products, that they are not taking handouts from developed countries, and that their governments are not run by donors nor beholden to them.

Donors have their own arguments for funding local manufacturing projects. One of the most common is a hope that local production of contraceptives can lead to sustainability and decreasing dependence upon donor aid for commodities. While donors do, of course, consider basic economic criteria in making decisions about local manufacture, they are also influenced by a constellation of other rationales. For example, it is generally agreed that UNFPA's investments in local production are often field-driven and do not have a strong profitability criterion. As a result, UNFPA has financed at least 17 local manufacturing projects in China, 6 in India, and 2 in Vietnam (UNFPA, 1995). In contrast, the World Bank, which has a much wider array of investment options, stricter economic criteria, and fewer obligations to developing country constituents, has no history of funding local manufacture of contraceptives.

Several donor representatives interviewed noted that the differences between UNFPA and the World Bank are not so much political as economic—UNFPA is traditionally sympathetic to

noneconomic arguments for local manufacture, whereas the World Bank has judged potential loans for local contraceptive manufacture on strict profitability criteria.

## 3.3 Quality Assurance

Along with profitability and market distortions, another production criterion is quality—as important for donors, governments, and consumers as it is for most manufacturers. Product quality is usually a high priority for multinational pharmaceutical firms, which do not want to see their established reputations and brands jeopardized by compromises on quality. Many factors may lead smaller local producers to sacrifice quality, including competition, shortages of capital to maintain quality control, and a desire to lower costs. In fact, because local producers often compete not only against imported contraceptives but also against low-cost donor-supplied contraceptives, the temptation may be strong to cut costs by compromising quality. In the manufacture of oral contraceptives, according to one observer, this problems may manifest itself in the form of poorly formed or misplaced pills and widely varying amounts of active ingredients.

Quality assurance in some developing countries is further compromised by outmoded production facilities and/or lax regulatory environments. Examples of such problems raised in the interviews conducted for this study include the use of unreliable, older machines in some production facilities in India, which results in production of condoms prone to failure or leakage, and lax oversight on the part of the Indian military, which has historically had the responsibility for condom testing and which has a reputation for casting a blind eye toward poor-quality products. Although the government of India has recently issued strict specifications for condom factory output, a lack of adherence to Good Manufacturing Practices is still cited as a barrier to quality contraceptive production (UNFPA, 1995).

Poor management and a lack of skilled human resources also contribute to poor quality. Quality assurance is crucial even during the earliest stages of local production. One company that manufactures diaphragms in Brazil continues to be hobbled by the fact that public perceptions about their product were formed from low-quality initial production runs, despite the fact that the product now routinely meets or exceeds relevant standards.

Quality is clearly affected by poor management, outdated machinery, keen price competition, and a lax regulatory environment, among other factors. Nonetheless, the direct cause of poor quality is usually poor manufacturing practices. In 1992, the World Health Organization's (WHO's) Expert Committee on Specifications for Pharmaceutical Preparations took the important step of publishing a detailed description of "Good Manufacturing Practices for Pharmaceutical Products" (WHO, 1992). This document, which has helped set standards for good practices, has been supplemented by "Requirements for the Quality Assurance of Hormonal Contraceptives" (WHO, 1995) and "Issues to

Consider in the Production of Hormonal Contraceptives" (WHO, 1994). Organizations such as UNFPA and PATH also have worked hard to improve manufacturing practices in their projects.

**Perspective**

### How Important is Quality?

The interviews conducted for this report uncovered a variety of opinions about quality. Most donor representatives argued that there should be no double standard for quality between developed and developing countries. One person was emphatic that it is ethically and politically wrong to support projects that produce goods of inferior quality.

Others embraced quality but were more pragmatic. One IUD manufacturer stated that quality is absolutely crucial for copper IUDs, not only for obvious safety reasons but also because if anyone in the world manufactures a poor-quality copper IUD, the entire world market could suffer. A former employee of a USAID cooperating agency expressed a strong feeling that donors that focus on new manufacturing projects are missing the best opportunities to "improve, enhance, and upgrade" existing companies, which are "off the USAID radar."

# 4. THE ROLE OF DONORS

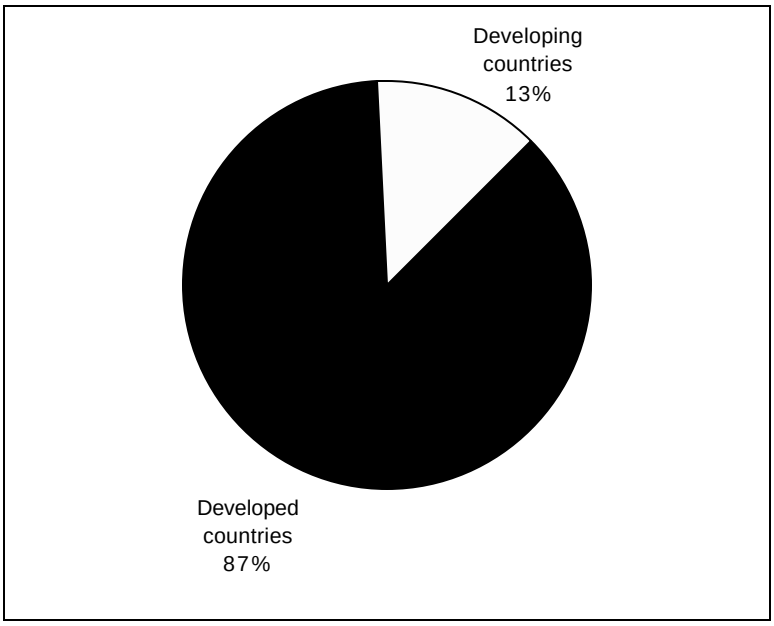
## 4.1 Donor Procurement

Donors' influence on the local manufacture of contraceptives manifests itself in several ways. Globally, the biggest effect may be a dampening one. In donor-assisted countries with sufficient technological infrastructure to support a pharmaceutical industry, private pharmaceutical firms must compete with the donated commodities available in the public sector, unless they produce *for* donors.

Production by local firms for donors also may be difficult, especially if donors refuse to buy locally manufactured products. The foremost example of this perennial problem for non–U.S. manufacturers is USAID's "buy American" policy. Many of the interviewees for this report were frustrated by this rule. One pharmaceutical company representative was recently disappointed to learn that his company's subsidiary in Mexico would not be able to bid on a USAID commodities contract despite his expectation that implementation of the North American Free Trade Agreement (NAFTA) would have opened the USAID competition to Mexico- and Canada-based firms.

Donor procurement is big business—but mainly for the largest multinational pharmaceutical firms. In 1995, the two biggest contraceptive commodity suppliers in the world, UNFPA and USAID, spent nearly $100 million on contraceptive purchases, only 13 percent of which went to developing country suppliers (Figure 4). By law, USAID purchases all of its commodities from U.S. suppliers. UNFPA spent $13 million for contraceptive commodities from developing countries—condoms from the Republic of Korea, condoms and IUDs from India, and oral contraceptives from Pakistan.

**Figure 4. Source of USAID- and UNFPA-Purchased Contraceptives, 1995**




Total = US$98 million

Source: UNFPA, 1996

## 4.2 Donor Funding

The largest donor-funded local manufacturing projects have been those initiated by UNFPA in China, India, and Vietnam. A variety of smaller projects also have been undertaken by UNFPA, bilateral donors including USAID, and donor-affiliated organizations such as PATH and the Population Council.

Donor involvement in local manufacture of contraceptives has generally been welcomed in the developing countries involved. However, the literature review and interviews conducted for this report highlight potential threats to the donor-recipient relationship in local manufacturing projects. These include the inability or refusal on the part of governments to purchase locally produced commodities.

For example, when the UNFPA–funded condom manufacturing facility in Vietnam, MERUFA, opened in the late 1980s, its was plagued by canceled orders from the Vietnamese government itself.[1]

The biggest potential problem between donors and local entities (including governments) may be complaisance in the face of poor manufacturing practices. Donors and their implementing agencies naturally insist on strict adherence to Good Manufacturing Practices in the knowledge that less rigorous standards would result in poor-quality products. Unfortunately, a lack of in-country expertise and the inherent inefficiencies of centralized production have been compounded by financial limitations and poor infrastructure. The result has been substandard quality assurance.

## 4.3 Donor Politics

Donors interact not only with manufacturers and governments but also with each other. The importance and value of local manufacturing of contraceptives is a hotly debated subject among donors. UNFPA has always been very supportive of local manufacture. Among the interviewees for this report, one noted that Japan and some European bilateral donors have historically favored local manufacture because they are sympathetic to "infant industry" arguments, but that Germany and the United Kingdom have not because they do not want to see their large pharmaceutical companies suffer from new competition.

UNFPA, USAID, and other donors do not always have the staff expertise to provide technical assistance to their projects (including the local manufacture of contraceptives) and may contract with organizations that specialize in these activities. Typically, these agencies are praised for the high quality of their work. However, interviews with donor representatives and others revealed a concern that these agencies sometimes work to serve their own interests. One agency came under fire for overestimating the size of local contraceptive markets in its feasibility studies. One manufacturing expert cautioned that donor agencies should not be put in charge of processes from which their organizations might directly profit.

[1] A recent UNFPA evaluation of this project indicates that government orders have resumed and that MERUFA is doing its best to meet them (UNFPA, 1995).

# 5. THE FUTURE OF LOCAL MANUFACTURING

What does the future hold for the local manufacture of contraceptives? Several competing trends make this question difficult to answer:

- Donors such as USAID are more reluctant to spend scarce funds to purchase contraceptive commodities and are phasing out many commodity programs.
- A global expansion in free trade may open foreign markets to multinational pharmaceutical companies that previously had been forced to build factories in order to operate in certain countries.
- Rising incomes, improved living standards, and infrastructure improvements in many developing countries may enable more people to purchase contraceptive commodities in the private market and may make local production more feasible.

Donors will no doubt continue to be involved in developing country manufacture of contraceptives, but the most successful donor ventures will likely be those initiated in collaboration with the private sector. Global trends toward economic liberalization will make government-owned production less common and will allow donors to assess local production opportunities by much stricter economic criteria. A key ingredient—one often missing in the past—will be competition.

Donors must insist that projects be funded only when the producers face market incentives that reward high-quality, efficient production. This may be happening now—one interviewee for this report indicated that UNFPA, the principal funder of such projects, may soon change its funding criteria due to the difficulties it encountered in implementing projects in China and Vietnam—poor manufacturing practices and unstable demand, respectively, as noted above.

Many of those interviewed for this report have the sense that, in an era of shrinking commodity donations, donors' responsibilities to developing countries do not end if the perfunctory assessment yields the conclusion that local production is unfeasible. A strong consensus emerged that it is misguided for donors to give lip service to the concept of "sustainability" while simultaneously neglecting to teach developing country governments how to efficiently procure commodities on the free market. The International Planned Parenthood Federation (IPPF) has attempted to address this problem by aiding its affiliates not only in initiating income-generating projects but also in making initial contacts with contraceptive manufacturers (IPPF, 1996). In addition, PATH and the USAID–funded Family Planning Logistics and Management (FPLM) Project have also emphasized the importance of teaching procurement skills.

Making decisions about local manufacture of contraceptives involves consideration of many factors, economic and technical as well as political and social. In particular, donors assessing local manufacturing ventures must explore and consider the interests of those involved in and affected by the potential project.

This paper provides some insight into what types of people and organizations are affected by and, in turn, can affect the ultimate success of donor-supported local manufacturing ventures. The review of global contraceptive demand and supply and the outline of market forces that affect local contraceptive manufacturing help identify the possible stakeholders in such ventures. The results of the interviews conducted for this paper give some indication of how disparate the interests of those stakeholders can be. Appendix 2 offers a checklist of some of the key questions that donors should consider when assessing the feasibility and advisability of local manufacturing partnerships. Exploring stakeholders' interests by asking these types of questions can help uncover potential obstacles to success that may not become apparent using technical feasibility studies alone.

## *APPENDIX 1: LIST OF INTERVIEWEES*

Interviews for this research, some of which were confidential, were conducted with one or more individuals from the organizations listed below.

### Manufacturers

- Famy Care, Ltd. (India)
- Finishing Enterprises, Inc. (USA)
- J.K. Enterprises (India)
- Schering AG (Germany)
- Wyeth-Ayerst (USA)

### Donors

- United Nations Population Fund (UNFPA)
- U.S. Agency for International Development (USAID)
- World Bank

### USAID–Funded Projects

- AIDSCAP (AIDS Control and Prevention Project)
- BASICS (Basic Support for Institutionalizing Child Survival)
- FPLM (Family Planning Logistics and Management)
- PROFIT (Promoting Financial Investments and Transfers)
- SOMARC (Contraceptive Social Marketing III)

### Private and Nonprofit Organizations

- Family Health International (FHI)
- Program for Appropriate Technology for Health (PATH)
- Rockefeller Foundation

## Others

- U.S. Centers for Disease Control and Prevention (CDC)
- University of California at Berkeley

## *APPENDIX 2: FACTORS TO CONSIDER IN ASSESSING LOCAL MANUFACTURING VENTURES*

### Private Manufacturers

- **U** Is the size of the market sufficient for multinational firms to enter?
- **U** Will multinational and/or local producers benefit from increases in the overall market?
- **U** Will multinational and local producers both lose private market share to donor-subsidized commodities?
- **U** Are multinational and local producers in direct competition?
- **U** Can multinational and local producers act together in joint ventures such as site licensing arrangements?
- **U** Are multinational firms concerned about patent infringement by independent local manufacturers?
- **U** Do the interests of multinational and local producers diverge on local trade policies?
- **U** Will multinational firms benefit more than local producers from a bigger public sector market?
- **U** Is adherence to strict quality regulation more difficult for local firms than for multinational firms?
- **U** Does the government enforce trade policies that penalize multinational firms?
- **U** Are imported multinational firms' products costly in terms of foreign exchange?
- **U** Do the efficiencies of scale of the prospective firm(s) and/or public sector pricing keep prices low enough to interest consumers?

### Donors

- **U** Is the donor subject to "buy local" policies that favor multinational producers?
- **U** Does the donor have the buying power to force public sector pricing on multinational firms?
- **U** Will the donor's bureaucracy deter the multinational firms?

- **U** Does the quality of locally produced contraceptives meet donor standards?
- **U** Are the costs associated with encouraging or funding local production prohibitive?
- **U** Is the Ministry of Health (MOH) convinced of the long-term advantages of donor-supported local manufacture?
- **U** Is the MOH willing to purchase locally produced contraceptives in lieu of receiving donated commodities?
- **U** Will local production benefit consumers directly through better access to contraception?
- **U** Will local production promote employment and otherwise stimulate the local economy and infrastructure?
- **U** Will local production benefit consumers indirectly through its impact on the local economy?
- **U** Is donor support of local manufacture of contraceptives a cost-effective means of helping the poorest consumers?

### Ministry of Health

- **U** Will the MOH purchase commodities from a multinational firm?
- **U** Does the MOH prefer to buy from local manufacturers when possible?
- **U** Does the MOH give preference to local firms in price bidding?
- **U** Will MOH regulations/policies deter the firm(s) from investing?
- **U** Can the MOH afford the prices charged by the prospective firm(s)?
- **U** Is the MOH dependent on donor funding for commodities?
- **U** Will local manufacture allow the MOH to better serve consumers with less expensive or more culturally appropriate contraceptives?
- **U** Will existing barriers and inefficiencies continue to prevent consumer access to quality MOH care regardless of availability of locally produced contraceptives?

### Consumers

- **U** Is there a consumer preference for imported products?
- **U** Will consumers desire the perceived higher quality of foreign brands?
- **U** Do locally produced contraceptives cost less than imports?
- **U** Are consumers interested in the prospective firm's or firms' products?
- **U** Is the quality of local products equal to that of imports?

**U** Is the quality of local products consistent?

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